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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,832	02/27/2002	Mustapha Abdelouahed	1440.1038-003	5718

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EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/19/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/084,832

Applicant(s)

ABDELOUAHED ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) 9-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-7 and 34-36 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant has added Claim 37 that will be included in the examination of Group 1.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Jean Amiral as evidenced by Thorpe et al (USP#6,312,694).

Jean Amiral discloses an isolated complex that includes heparin binding proteins platelets (col. 4, line 31). These platelets proteins are antigenic fractions that are lysed from blood platelets and have a strong affinity for heparin that can induce anti-heparin antibodies (col. 5, lines 13-29). The drug heparin is mixed with a complex of antigenic substances to determine the presence of antibodies (see summary). Heparin binding proteins were isolated from mammalian blood during clinical trials (col. 11, lines 10-35).

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Although Jean Amiral does not particularly point out what the platelet proteins are, evidence is provided by Thorpe et al, that thrombospondin-1 and platelet factor 4 are found in platelet alpha granules and are known to associate with heparin (See USP#6,312,694, col. 99, lines 47-50). Jean Admiral discloses that heparin bind to platelet complexes, therefore it is inherent that thrombospondin-1 and platelet factor 4 will be included in that complex. Jean Amiral also discloses an assay kit to determine a heparin-induced thrombopenia (col. 10, lines 10-67). The platelet factor 4 and thrombospondin-1 are present at a ratio determined to be optimal for recognition especially since Thorpe et al discloses that these heparin binding proteins associated with heparin. Claims 6 and 7 will not be given patentable weight because the claims are drawn to a method of making the product.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Gogstad et al (British Journal of Haematology, Apr 1983, Vol. 53, (4), pages 563-73)

Gogstad et al teaches a complex of platelet proteins that were isolated from alpha-granules. These platelet proteins comprise of platelet factor 4 and thrombospondin bound to immobilized heparin. Platelet proteins were applied to

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crossed immunoelectrophoresis against anti-platelet antibodies (see whole abstract).

Patenable weight will not be given to claims 6 and 7 because the claims are drawn to a method of making the product.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jean Amiral as evidenced by Thorpe et al in view of Zuk et al (USP#4,281,061).

The teachings of Jean Amiral as evidenced by Thorpe et al are set forth above and differ from the instant claims in not teaching all the components of a kit.

However, Zuk et al teaches that "as a matter of convenience the reagents of an immunoassay can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest" (col. 22, lines 63-66).

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take reagents such as the anti-hep antibody and the heparin binding proteins as taught by Jean Amiral and evidenced by Thorpe et al and formulate them into a kit because Zuk et al teach that it is convenient to do so and one

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can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which can eliminate the variability that can occur when performing the assay.

Conclusion

8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Aaron Tomer teaches a flow cytometry assay for heparin-induced thrombocytopenia (USP#5,763,201).

B. Guo et al teaches heparin-binding peptides from the type 1 repeats of thrombospondin (The Journal of Biological Chemistry, Vol. 267, No. 27, Issue of September 25, 1992, pages 19349-19355).

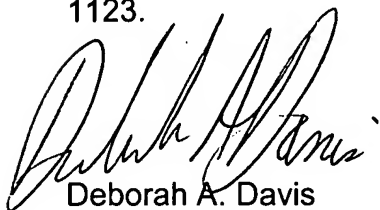
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

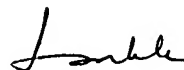
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123.



Deborah A. Davis
CM1, 7D16
June 13, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

06/11/03